Non-technical Abstract

Colon cancer is a leading cause of cancer death in the United States and in Europe. For most patients, the cancerous growth can be removed by surgery, but some individuals develop a recurrence of the cancer despite surgery, radiation treatment and chemotherapy. In such patients, the cancer is likely to spread to the liver, and less than 5% will survive beyond 16 months despite aggressive chemotherapy. Gene therapy may be a viable treatment option. We have developed a gene therapy vector (known as Mx-dnG1) which, when injected into the bloodstream, can seek out the cancer and accumulate in areas where the cancer has spread. Recently, we demonstrated significant reductions in the size of the tumors in the livers of Mx-dnG1 vector-treated mice compared to that of control mice. A built-in safety feature of this retroviral vector is that it lacks the ability to replicate and will only insert its genetic cargo into rapidly dividing cells such as cancer cells while sparing normal cells. The goal of the clinical trial is to evaluate the safety of the Mx-dnG1 vector in patients with colon cancer that has spread to the liver. The Mx-dnG1 vector will be injected into the liver artery through a pump for 6 hrs, daily for 5 days. The dose of the vector will be increased according to protocol specifications. While the clinical trial is primarily a safety study, it is possible that the treatment will shrink the cancer and/or inhibit its growth.